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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,102	12/27/2004	Imao Mikoshiba	Q85257	9490

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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03/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,102	MIKOSHIBA ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14 and 24-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/14/08*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed January 10, 2008 has been received and entered into present application. Claims 1-11 and 15-23 were canceled and claims 24-36 were added by applicant. Thus claims 12-14, and 24-36 are pending.

Applicants' arguments, filed January 10, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated Ohnota et al. (Novel Rapid- and Short-Acting Hypoglycemic Agent...) already of record, for the reasons set forth at pages 6-10 of previous office action dated July 13, 2007, of which reasons are herein incorporated by reference.

Claim 12 has been amended to a method for lowering postprandial blood glucose level and fasting blood glucose levels without causing prolonged hypoglycemia, comprising administering to a type II diabetic patient 5 to 45 mg of mitiglinide or salt thereof. Claim 13, further limits the dosage range to 5-22mg. The rejection of July 13, 2007 in which claims 12 and 13 were rejected over 35 U.S.C. 102(b) as being anticipated Ohnota et al. still applies, as Ohnota et al. teaches a method of administering mitiglinide calcium hydrate (KAD-1229) to type II diabetic patients (page 490, paragraph 1). The dosage ranges used in Ohnota et al. were 0.3-3.0 mg/kg as discussed before would translate to 16-65mg for a 120lb person, or in the case of the 10kg dogs used in Ohnota et al. (page 490, paragraph 5) dosage ranges of 3-30mg. Applicant claims a "patient" but does not specify that it cannot be a rat or dog (such as those tested in Ohnota et al.). Since dogs get diabetes, it is a reasonable interpretation of "patient". Furthermore, Ohnota et al. teaches treatment of humans with KAD-1229 and although specific dosages were not tested on humans, the dosage ranges are often the same, dependent on body weight. Thus, Ohnota et al. teaches a method of administering 5 to 45mg of mitiglinide calcium hydrate to a type II diabetic patient, and that would inherently lower postprandial and fasting blood glucose levels such as claimed and claims 12 and 13 are anticipated by Ohnota et al.

Applicant argues that their method accomplishes things not taught in the prior art, such as the differences between simple glycemic control and lowering postprandial blood glucose levels. However, the method as claimed, consists of administering mitiglinide to a type II diabetic patient, which Ohnota et al. teaches. The method of

Ohnota et al. would be expected to accomplish everything claimed in the instant application because the same drug is being administered to the same patient with the same dosages. Thus what is being claimed is anticipated by Ohnota et la.

Claim Rejections - 35 USC § 103 (new grounds of rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-14, 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohnota et al. (Novel Rapid- and Short-Acting Hypoglycemic Agent...) already of

record, for the reasons set forth at pages 6-10 of previous office action dated July 13, 2007, of which reasons are herein incorporated by reference.

Due to amendments to claims 12-14 and the addition of claims 24-36, new grounds of rejection are caused by amendment. Claims 12-14 claim a method of administering mitiglinide or pharmaceutically acceptable salt to a type II diabetic patient before a meal with a dosage of 5-45 mg(claim 12), 5-22mg (claim 13), or 10-11mg (claim 14). As discussed above Ohnota et al. teaches dosages of 0.3-3mg/kg which would range from 3-30mg for a 10kg dog (as administered by Ohnota et al.). Regardless of whether the patient is a dog or a human, it would have been obvious to one of ordinary skill in the art at the time of the invention that dosages can be optimized and such small differences are within the range of routine experimentation. Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to mg/day dosage amounts, such a motivation is nonetheless relevant.

Furthermore, applicant had argued that the instant application involves more than merely lowering blood glucose levels as taught by Ohnota et al. however, the method of Ohnota et al. is the same as the method claimed, and one of ordinary skill in the art at the time of the invention would have known that by administering the same drug as the

same/similar dosages to a type II diabetic patient would accomplish the same things and thus claims 12-14 are unpatentable over Ohnota et al.

In claim 24, applicant claims the type II diabetic patient treated in claim 12 is a patient who's HbA_{1c} values is not less than 6.5% and the 1-2 hour value of the postprandial plasma glucose is not less than 200 mg/dL even after more than 8-week therapy. Applicant has added a very specific patient, however that patient is still a type II diabetic patient who would benefit from the treatment of claim 12 and Ohnota et al., and although Ohnota et al. does not disclose such specifics, it would be obvious to one of skill in the art at the time of the invention that a patient with those levels would also be in need of lowering postprandial blood glucose levels and thus the method of Ohnota et al. would be expected to help the patient of claim 24, and claim 24 is unpatentable over Ohnota et al.

Claims 25-32 claim the method of claims 12-14, and 24 in which the mitiglinide is administered 5 or 10 minutes before the start of a meal. Ohnota et al. does not teach administering their composition at any particular time, however administering glucose regulating drugs to diabetics before 0-15 minutes before meals is common and well known in the art. Furthermore, Ohnota et al. teaches that the peak levels of their composition were reached at 30 mins, and thus it would be obvious to one of ordinary skill in the art at the time of the invention that administration just prior to the meal would lead to desirable effects of a peak mitiglinide level occurring at the time in which glucose levels start to spike. Thus claims 25-32 are unpatentable over Ohnota et al.

Claims 33-36 claim that the composition of mitiglinide is administered three times per day before the start of each meal for 4 weeks or more. Since it is common to eat three meals per day, and thus taking something before each meal of the day would have been obvious to one or ordinary skill in the art. continuing the therapy for four weeks or more would also be obvious to one of skill in the art at the time of the invention, as most diabetic blood glucose treatments are administered continuously as maintenance drugs. Thus claims 33-36 are unpatentable over Ohnota et al.

Additionally, applicant makes argument that neither Ohnota et al. or Ouchi et al. teach the "unexpected effects of the present invention" (page 10 of remarks submitted Jan 10, 2008). However, applicant has not shown unexpected effects, and one of ordinary skill in the art at the time of the invention would expect the method of Ohnota et al. to produce the same effects as that of the instant invention and applicant has not shown how their invention produced unexpected effects.

Conclusion

Rejection of claims 12-14 is deemed proper and is **maintained.** New rejections of claims 24-36 are necessitated by amendment.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-

3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614